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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Revised Date 1-3-05
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Signature J. Cooke

[Docket No. 2004N-0534]

Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD

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20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

Format and Content Requirements for Over-the-Counter (OTC) Drug Product Labeling—(OMB Control Number 0910–0340)

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA amended its regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed OTC drug products. The rule requires OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. The rule is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. FDA concludes that the labeling statements required under this rule are not subject to review by OMB because they are originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)) and therefore do not constitute a collection of information under the PRA (44 U.S.C. 3501 *et seq.*).

Section 201.66 of the labeling requirements (21 CFR 201.66) requires all OTC drug manufacturers to format labeling as set forth in paragraphs (c) and (d). FDA has learned from the industry that OTC drug product manufacturers routinely redesign the labeling of their products as part of their usual and customary business practice. The rule provides varied timeframes for implementing the labeling requirements. Therefore, the majority of respondents will be able to format OTC drug product labeling in accordance with § 201.66 as part of their routine redesign practice, creating no additional paperwork or economic burden.

In discussing the collection of information under the PRA in the final rule (64 FR 13254 at 13274 to 13276), FDA stated that of the 39,310 stock keeping units (SKUs) (individual products, packages, and sizes) currently marketed under a final monograph, approximately 32 percent, or 12,573 products, may necessitate labeling changes sooner than provided under their usual and customary practice of label design. FDA estimated that of the 400 respondents who produce OTC drug products, including the 12,573 products described above, each may be required to respond approximately 31.4 times to this rule outside of their usual and customary practice. Each response was estimated to take, on the average of, 4 hours, for a total of 50,292 hours per year. The burden was expected to be a one-time burden.

FDA stated that although the usual and customary practice of label redesign would minimize the burden for the remaining 68 percent of SKUs currently marketed, or 26,737 products, additional time may be necessary for each company to make the format changes under this rule. FDA estimated that of the 400 respondents who produce OTC drug products, each may be required to respond approximately 66.8 times to bring the 26,737 products into compliance with this rule. FDA estimated that each response for this group will take an average of 2.5 hours for a total of 66,842 hours. The burden was expected to be a one-time burden.

Finally, FDA estimated that approximately 61 respondents hold new drug applications (NDAs) and abbreviated new drug applications (ANDAs) (41 NDA holders and 20 ANDA holders) for which supplements and amendments will be required. FDA expected that 522 submissions (350 to NDAs and 172 to ANDAs) will be required for labeling changes under § 201.66(c) and (d), which averages to 8.5 submissions per respondent. FDA estimated that each

submission will take an average of 2 hours to prepare for a total of 1,040 hours annually. The burden was also expected to be a one-time burden.

Because the final rule was issued on March 17, 1999, FDA extended the May 16, 2001, compliance date for products subject to drug marketing applications approved before May 16, 1999, and for products subject to an OTC drug monograph finalized before May 16, 1999, by 1 year to May 16, 2002 (with a corresponding extension of the May 16, 2002, compliance date for products with annual sales of less than \$25,000 to May 16, 2003) (65 FR 38191, June 20, 2000). Products subject to an OTC drug monograph finalized on or after May 16, 1999, had to comply within the period specified in the final monograph. However, if a monograph had not been finalized as of May 16, 2002, then the products have to comply as of the first major labeling revision after May 16, 2002, or by May 16, 2005, whichever occurs first.

Since March 17, 1999, FDA has published six major final rules on OTC drug monographs and several minor amendments to existing final monographs. The following are the six major final rules and their date of publication:

- Sunscreen drug products (May 21, 1999),
- Cough-cold combination drug products (December 23, 2002),
- Antidiarrheal drug products (April 17, 2003),
- Ingrown toenail relief drug products (May 7, 2003),
- Skin protectant drug products (June 4, 2003), and
- Antiperspirant drug products (June 9, 2003).

The effective date for the final monograph for OTC sunscreen drug products and for the implementation of the new labeling format for these products has been stayed indefinitely (65 FR 36319, June 8, 2000, and 69 FR 53801, September 3, 2004). The effective date for products subject to the final rules on the other OTC drug monographs to implement the new labeling format

will occur by the end of 2004, except for a small number of products with annual sales less than \$25,000. Those products will have until June 2005 to implement the new labeling format. These dates should enable manufacturers to coordinate the relabeling required by the final monographs with the relabeling required by the OTC drug product labeling final rule.

FDA previously estimated that 12,573 out of 39,310 SKUs were affected by the March 17, 1999, OTC drug product labeling final rule. Based on information in the six final rules issued since that time, FDA estimates that 11,250 additional SKUs have already been affected by the OTC drug product labeling final rule. Thus, 15,487 SKUs remain to be affected by the OTC drug product labeling final rule. All of these will need to implement the new labeling format by May 16, 2005, except for the sunscreen drug products that are currently deferred.

As the number of products remaining to be affected by the OTC drug product labeling final rule is close to the number of products affected at the time of the May 17, 1999, publication of that final rule, FDA is listing the same numbers of respondents, annual frequency per response, and total annual responses in this notice.

FDA believes the hours per response and total hours may be less than the numbers stated in the final rule for several reasons. First, respondents have made a number of inquiries to FDA already since the final rule was issued in 1999. FDA's experience with these inquiries is that inquiries have been less than 2.5 or 4 hours per response, generally averaging 0.25 to 0.5 hour per inquiry. Second, respondents have gained significant experience with the final rule since 1999, reducing their need to make additional inquiries. Third, FDA issued a draft guidance for industry entitled "Labeling Over-the-Counter

Human Drug Products; Updating Labeling in ANDA's" (66 FR 11174, February 22, 2001), which included a number of labeling examples to assist holders of ANDAs for OTC drug products and manufacturers of reference listed drugs (RLDs) for the ANDAs to implement the new OTC drug product labeling regulation. FDA issued a final guidance for industry on October 18, 2002 (67 FR 64402). This guidance should have reduced some of the hours per response and total hours for some NDA and ANDA holders. However, FDA is not currently able to estimate how much time has been reduced. Accordingly, FDA is listing the same hours per response and total hours in this notice as appeared in the March 17, 1999, final rule.

FDA estimates the burden of this collection of information as follows:

Table 1.—Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
201.66 ²	400	31.43	12,573	4	50,292
201.66	400	66.8	26,737	2.5	66,842
201.66(c) and (d) ²	61	8.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
Total					120,578

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

²One-time burden.

Dated: 12-28-04

December 28, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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> [FR Doc. 04-⁵????⁵ Filed ??-??-04; 8:45 am]

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